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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/068,253 06/09/98 SHIMURA

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EXAMINER

MOEZIE, F

ART UNIT

PAPER NUMBER

1653

DATE MAILED:

05/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/068,253

Applicant(s)

SHIMURA et al

Examiner

F. MOEZE

Art Unit

1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/15/01 and 12/14/00.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5, 8-11, and 13-15 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5, 8-11, and 13-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

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DETAILED ACTION

STATUS OF CLAIMS

Claims 2-5, 8-11 and 13-15 are pending prosecution in this Office action.

HISTORY OF PROSECUTION

Claims 1-7 were originally filed, wherein claims 1-6 were drawn to a composition and claim 7 was drawn to a method of use.

In the Preliminary Amendment dated 13 May 1998, paper no.5, claims 8-11 (dependent from claim 7) were added.

In the first Office action on the merits mailed 3/2/99, paper no. 6, claims 1-11 were rejected under 35 U.S.C. 112, second paragraph and 35 U.S.C. 103 (a)..

In response to the Office action, applicant filed an Amendment (received 28 May 1999, paper no. 7), wherein, claims 1-5, 7 and 9 were amended and claim 6 was canceled.

In the second Office action on the merits of the claims mailed 8/18/99, paper no 8, claims 1-5 and 7-11 were rejected under 35 U.S.C. 112, Second paragraph, claim 1 was rejected under 35 U.S.C. 102 (b) and claims 2-5 and 7-11 were rejected under 35 U.S.C. 103 (a).

In response to the second Office action, applicant filed an Amendment (received 1/21/00, paper no. 10), wherein claim 1 was canceled and a new composition claim, claim 12 was added. Form PTO-1449 was also submitted.

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In the third and Final Office action on the merits of the claims mailed 4/13/00, paper no. 11, claims 2-5 and 7-12 were rejected on various grounds of 35 U.S.C. 112, first and second paragraphs and 35 U.S.C. 102 (b)/103 (a). The earlier rejection of the claims under 35 U.S.C. 103 (a) was maintained.

In a follow up interview with the Applicants' representative on 4/13/00, applicant was to review and correct the terminologies related to the polymers and distinguish the claims over the art, by adding collagen free, if applicable, to the claims.

In response to the Final rejection, applicant filed an Amendment (31 July 2000, paper no. 14) wherein, claim 12 was amended to include a further limitation, i.e., "collagen free". **Claim 7 was canceled** and a new method claim (claim 13) was added to replace claim 7. This new claim **did not include the limitations** deemed necessary and included in the compositions claim(s).

The Finality of the Final rejection was withdrawn, 8/15/00, paper no. 15, and the amendment filed 7/31/00, paper no. 14, was entered.

In the Amendment filed 11 August 2000, paper no. 16, claim 12 was canceled and a new composition claim, claim 14 was added. **Claim 7 was canceled** and a new method claim, claim 15, was added to replace claim 7. This new method claim **did not include the limitations** agreed upon.

In a follow up interview, 8/30/00, applicants' attention was called upon the SEQ ID NO:1 at page 18, line 17, and the need for compliance with the amino acid sequence listing requirements. In addition to correcting the specification regarding errors and/or inconsistencies.

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In a series of miscellaneous actions which followed, applicant submitted Sequence ID Listing which was finally good technically and entered into the data base (5/10/01).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**COMPLIANCE WITH THE REQUIREMENTS FOR PATENT APPLICATIONS
CONTAINING AMINO ACID SEQUENCE DISCLOSURES**

This application fails to fully comply with the requirements as set forth in the earlier Notice To Comply with the Amino Acid Sequence Disclosures because:

Note: Upon compliance with the requirements applicant must also amend the application to provide the SEQ ID NOS in THE SPECIFICATION (at least in the first occurrence, in ALL CLAIMS, EXAMPLES, TABLES and CLAIMS.

Current Claims Status:

Independent claim 14 (new, added 8/11/00), drawn to a composition, and claims 2-5 are dependent thereon.

Claim 13 (new, added to **replace canceled claim 7**), drawn to a method of use, are dependent from the **canceled claim 12**.

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Claim 15 (new, added to **replace canceled claim 7**), drawn to a method of use and claims dependent thereon (claims 8-11).

REJECTION - 35 U.S.C. 112, FIRST PARAGRAPH

Claims 13 and the claims dependent thereon are rejected under 35 U.S.C., first paragraph, as containing New matter. The newly added term is “defect” at the end of the claim. Applicant should specifically point out the support for the amendments, see MPEP Sec. 714.02 and 2163.06.

REJECTION - 35 U.S.C. 112, SECOND PARAGRAPH

Claims 2-5 and 14 are rejected under 35 U.S.C. 112, second paragraph, regarding the terminology employed to define the molecular weight of the polymers. See below for suggestions.

Claims 10 and 11 are duplicative of one another. Cancellation of one of the claims is suggested.

Claim 13 and the claims dependent thereon, claims 8-11 and 15 are indefinite and improper as they depend from claim 12, a canceled claim.

In claims 13, line 3 and claim 15, lines 2-3, “the” or “said” should be substituted for “a” in the second occurrence of “a warm-blooded animal”.

REJECTION - 35 U.S.C. 103 (a)

Claims 8-11, 13 and 14 are rejected under 35 U.S.C. 103 (a) as being unpatentable over WO 94/1484 in view of JP 62-13546 or Ron et al for the reasons cited in the earlier Office action.

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mailed 8/18/99. Incorporation of all the limitations cited in the independent composition claim into the method claim(s) or drawing the method claims so that they would depend on the composition claims could overcome this ground of rejection.

SEQUENCE LISTING entered 5/10/01 is objected to as it introduces New Matter into the specification. Reference made to WO 95/04819 in the sequence Listing disclosures is not a properly incorporated reference into the specification. For proper Incorporation by Reference into the specification, see **MPEP 608.01 (p)**.

Applicant is required to cancel the new matter in the response to this Office action.

RESPONSE TO COMMUNICATION received 2/15/0, paper no. 21.

The specification is objected to under 35 U.S.C. 132 because it introduces New matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added and/or deleted material which is not supported by the original disclosure is as follows: The changes made at page 14, [a) deletions and b) insertions], constitute New Matter for the following reasons: a) for the deletions, there is no convincing reason given as to why the original disclosure is found defective at this time and the indicated paragraphs has to be deleted and b) the paragraphs entered on page 14, lines 3-7 and 16-20 also constitute New matter. Furthermore, the paragraphs inserted are not in accordance with the proper Incorporation by Reference. See, **MPEP 608.01 (p)** for guidance.

The claims are rejected as being based on an application which is objected to.

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RESPONSE TO REMARKS and the Supplemental Amendment filed 12/14/00. The amendment refers to a reference which is cited in the specification at page 14, lines 1 and 2. However, the later SEQ IDS (which have been entered in the data base) make reference to WO 95/04819. The cited WO 95/04819 reference belongs to a different entity. Applicant has to point out the support for the reference in the specification and properly incorporate the pertinent parts of the cited reference into the specification according to MPEP 608.01 (p). Currently, the entries to the specification and the entry of the sequences are considered New Matter.

The New Matter rejection of the claims as applied in the earlier final rejection (now finality withdrawn) regarding the introduction of the temperature limitations and “agent” is withdrawn in view of the applicants’ amendment and remarks filed Jan. 21, 2000.

The rejection of the claims under 35 U.S.C. 112, second paragraph, regarding the Molecular Weight of the polymers, is maintained because the terminology regarding the MW of the polymers is inconsistent and incorrect. Applicant is advised to employ the language of the specification throughout, wherein at page 6, lines 22-25 reference is made to the separate parts of the polymer as follows:

“the polyethylene glycol as a constituent of said polyoxyethylene-polyoxypropylene glycol has a molecular weight of about 1,500-4000 and an ethylene oxide content of about 40-80% per molecule”.

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The correct and consistent language should be maintained throughout the application (specification and the claims).

RESPONSE TO THE AMENDMENT AND REMARKS filed 8/11/00 under Rule 116. New claim 14 (not designated new) was added and claim 12 canceled. New claim 15 (not designated new) have been added and claim 7 canceled. The merits of the new claims 14 and 15 have been addressed herein above.

RESPONSE TO THE COMMUNICATION filed 31 July 2000, paper no. 14.

The specification is objected to under 35 U.S.C. 132 because it introduces New matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure are as follows: The entries at pages 14 and 18 constitute New Matter for the following reasons:

The incorporation of the necessary parts of the reference must occur by the insertion of its contents into the instant specification. This objection is currently moot due to the cancellation of the New matter material.

Additionally, specification is objected to because the definition for the polymers is not consistent throughout the specification. See above for explanation.

Claims are rejected as being based on a specification which has been found objectionable.

CONCLUSION


No claim is allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication should be directed to F.T. Moezie at telephone number (703) 305-4508 or Mr. LOW (SPE) at 308-2923.


F. T. MOEZIE, Ph.D.
PRIMARY EXAMINER
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